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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,904	07/07/2005	Robert R Redfield	014835-77.00-015	9067

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
09/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,904	REDFIELD ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7,10-12,15-18,23,25-27,30,33,35 and 37-47* is/are pending in the application.

4a) Of the above claim(s) *11,12,15-18,23,25-27,30,33,35 and 37-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of August 4, 2010 made to the office action filed March 4, 2010. Claims 1, 3, 5, 6, 7, 10-12, 15-18, 23, 25-27, 30, 33, 35 and 37-47 are pending. There are no new claim amendments. Claims 11, 12, 15-18, 23, 25-27, 30, 33, 35 and 37-47 are withdrawn.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejections were found not persuasive, thus the rejections are upheld and repeated below.

The Examiner addressed Applicant's arguments below.

The claims are drawn to the use of a composition for increasing concentrations of chemokines to reduce entry of HIV virus into mononuclear cells through binding of chemokine binding receptors and wherein the composition is administered in a cyclic therapy program. The intended use does not get patentable weight in composition claims. The claims are only treated on the merits as related to a composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 1, 3, 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hancock (US 2002/0019345 A1) in view of Baba et al. (Proc. Natl. Acad. Sci. USA, May 1999, vol. 96, pp. 5698-5703).

Hancock teach a method for inhibiting the rejection of transplanted grafts comprising an effective amount of an antagonist of CCR5 and an effective amount of an immunosuppressive agent (see abstract and claims 1, 6 and 13). Immunosuppressive agents include rapamycin (see paragraph 60; addresses claims 1 and 3). The composition can be administered orally, parenterally, rectally, nasally or topically (see paragraph 70; addresses claim 7). The drugs can be taken at the same time (see paragraph 67). An effective amount of the drugs is the amount sufficient to achieve a desired therapeutic effect (see paragraph 68; addresses claim 1).

Hancock does not teach TAK 779 (claims 1, 5 and 6).

Baba et al. teaches that TAK-779 is a small-molecule, nonpeptide that is a specific CCR5 antagonist (see title and abstract).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the compositions of Hancock et al. and TAK 779 because TAK 779 is a small molecule that specifically antagonizes CCR5.

In regards to the effective amount of the G1 phase arresting compound sufficient enough to increase concentrations of extracellular beta-chemokines, Hancock teaches this limitation because the effective amount of the drugs is the amount sufficient to achieve a desired therapeutic effect (see paragraph 68). Thus, it is within the skill of the art to determine the effective amount to obtain the desired therapeutic effect.

The composition of claim 1 is obviously taught by Hancock in view of Baba et al., thus claim 10 is taught.

2) Claims 1, 3, 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vezina (WO 94/05300) in view of Baba et al. (Proc. Natl. Acad. Sci. USA, May 1999, vol. 96, pp. 5698-5703).

Vezina teach methods and compositions for treating the pregression of an HIV infection comprising administering rapamycin and another anti-HIV agent (see abstract and claims 1 and 3; addresses claims 1 and 3). The compositions can be administered orally or parenterally (see claims 7 and 8; addresses claim 7).

Vexina does not teach TAK 779 (claims 1, 5 and 6).

Baba et al. teaches that TAK-779 is a small-molecule, nonpeptide that is a specific CCR5 antagonist with highly potent and selective anti-HIV-1 activity (see title and abstract).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the compositions of Vezina and TAK 779 because TAK 779 is a specific CCR5 antagonist with highly potent and selective anti-HIV-1 activity. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

In regards to the effective amount of the G1 phase arresting compound sufficient enough to increase concentrations of extracellular beta-chemokines, it is within the skill of the art to determine the effective amount to obtain the desired therapeutic effect.

The composition of claim 1 is obviously taught by Vezina in view of Baba et al., thus claim 10 is taught.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant argues that the prior art does not disclose or suggest all elements of the claims, particularly the use of an antiviral agent that inhibits entry of HIV into effected cells. Further an "effective amount" of a CCR5 antagonist is not taught as defined in the specification. The Applicants argue that they have shown improvement far surpassing any results shown in Vezina or Baba because of the impressive efficacy with the combination of RAPA and TAK 779. This specific combination provides for a surprising reduction in replication of HIV-1 versus the individual compounds. Thus, the Applicant would like the method claims rejoined with the composition claims. The Examiner has shown a non-statutory hindsight analysis.

The Examiner disagrees because as noted in the previous office action and above, the intended use does not get patentable weight in composition claims. The claims are only treated on the merits as related to a composition. The reasons for combining the prior art does not need to the same as the Applicant's. Thus, the "effective amount" is the amount sufficient to achieve a desired therapeutic effect (see Hancock, paragraph 68). In regards to a rejoinder, Hancock and Vezina teach a pharmaceutical composition comprising rapamycin in combination with a CCR5 antagonist or another anti-HIV agent. Baba et al. provides the motivation for choosing the elected CCR5 antagonist (i.e. anti-HIV agent), TAK-779. Thus, since the product

claims are not deemed patentable, rejoinder of the method claims are not deemed proper. In regards to the Applicant's unexpected results, it is noted that evidence of unexpected results is required to be reasonably commensurate in scope with the claimed invention. See, e.g., In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983). In this case, the current claims are broad were as the unexpected results are demonstrated with a very specific combination. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/
Examiner, Art Unit 1627

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627